4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-P-0527]

Determination That DURANEST (Etidocaine Hydrochloride) Injection, 0.5%, and Five Other DURANEST Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the DURANEST (etidocaine hydrochloride) drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to these drug products if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

Rachel Bressler,

Center for Drug Evaluation and Research,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 51, rm. 6302,

Silver Spring, MD 20993-0002,

301-796-4288.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

The drug products listed in the table in this document are no longer being marketed. DURANEST is indicated for infiltration anesthesia, peripheral nerve blocks (e.g., brachial

plexus, intercostal retrobular, ulnar, inferior alveolar), and central nerve block (i.e., lumbar or caudal epidural blocks).

Application No.	Drug	Applicant	Initial Approval Date
NDA 17-751	DURANEST (epinephrine bitartrate; etidocaine hydrochloride) Injection 1%	AstraZeneca Pharmaceutical	August 30, 1976
Do.	DURANEST (epinephrine bitartrate; etidocaine hydrochloride) Injection 1.5%	Do.	Do.
Do.	DURANEST (epinephrine; etidocaine hydrochloride) Injection 0.5%	Do.	Do.
Do.	DURANEST (etidocaine hydrochloride) Injection 0.5%	Do.	Do.
Do.	DURANEST (etidocaine hydrochloride) Injection 1%	Do.	Do.
NDA 21-384	DURANEST (epinephrine bitartrate; etidocaine hydrochloride) Injection 1.5%	DENTSPLY Pharmaceutical	Do.

The drug products listed in the table in this document are currently listed in the "Discontinued Drug Product List" section of the Orange Book. Lachman Consultant Services, Inc. submitted a citizen petition dated September 25, 2008 (Docket No. FDA-2008-P-0527), under 21 CFR 10.30, requesting that the Agency determine whether DURANEST (etidocaine hydrochloride) Injection, 0.5% and 1%, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not request a determination for the other DURANEST drug products listed in the table in this document, those drug products have also been discontinued. On our own initiative, we have also determined whether those products were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that the DURANEST drug products listed in the table in this document were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that the DURANEST drug products were withdrawn for reasons of safety or effectiveness. We have

carefully reviewed our files for records concerning the withdrawal of the DURANEST drug products from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the products were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the DURANEST drug products listed in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to any of the DURANEST drug products listed in the table in this document may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-6039 Filed 03/12/2012 at 8:45 am; Publication Date: 03/13/2012]